

REMARKS

In response to an Office Action, imposing a species election requirement on the claims of the above-referenced patent application, Applicant hereby provisionally elects:

species (i): a rod, as the stabilizing element, reading on claims 1, 2, 4-25, and 43;

species (vi): a straight joint, as the joint, reading on claims 1-4, 7-10, 12-24 and 43; and

species (x): a pedicle screw, as the connector, reading on claims 1-25 and 43;

and Applicant traverses the requirement with respect to species (i), (ii) and (iii); species (v), (vi), (vii), and (viii); and species (x) and (xi). Applicant asserts that claims 1 and 21 are independent claims that are generic to all of the purported species. When either one or both of claims 1 and 21 are found allowable, Applicant requests joinder of all purported species pursuant to 37 C.F.R. § 1.141.

Applicant respectfully requests reconsideration and withdrawal of the traversed species election for the reasons discussed below.

I. Claim Amendments

Claims 26-42 and 44 are requested to be cancelled. No claims have been added. No new matter is added by way of amendment. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. Applicant expressly reserves the right to timely file continuing applications based upon the canceled subject matter.

After amending the claims as set forth above, claims , Claims 1-25 and 43 will be pending in this application.

I. Species Election Requirements

A. The Examiner's View

In requiring an election of species, the Examiner has stated that the “species are independent or distinct because they are separate embodiments, they have different physical forms, and they have different specific modes of operation” (Office Action, page 3). However, according to M.P.E.P. § 808.02, “where the inventions as claimed are shown to be independent or distinct under the criteria of M.P.E.P. § 806.05(c) - § 806.06, the examiner, in order to establish reasons for insisting upon restriction, **must explain** why there would be a serious burden on the examiner if restriction is not required. Thus, the examiner must show by appropriate explanation one of the following: (A) Separate classification thereof...(B) A separate status in the art when they are classifiable together...(C) A different field of search.” (Emphasis added.) The Examiner has not provided any of the above for any species.

B. The Election Requirements

According to M.P.E.P. § 806.04:

Where an application includes claims directed to different embodiments or species that could fall within the scope of a generic claim, restriction between the species may be proper if the species are *independent* or *distinct*. However, 37 CFR 1.141 provides that an allowable generic claim may link a reasonable number of species embraced thereby.

(Emphasis added.) In view of the explanation of a restriction requirement above, Applicant respectfully submits that for at least those species to which the traversal applies, the species identified by the Examiner are neither independent or distinct. The Examiner has a burden to show that the species are independent or distinct in order to merit the election requirement. Applicant submits that the Examiner has failed to meet this burden and that the species to which the traversal applies are neither independent nor distinct. The criteria to show independent and distinct species are set forth, in part, below:

According to M.P.E.P. § 802.01(II):

Two or more inventions are related (i.e., not independent) if they are disclosed as connected in at least one of design (e.g., structure or method of manufacture), operation (e.g., function or method of use), or effect.

According to M.P.E.P. § 806.04(b):

Where inventions as disclosed and are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such those covered in MPEP § 806.05 - § 860.05(j). If restriction is improper under either practice, it should not be required.

The requirements for distinctness are set forth in § 806.05(j).

To support a requirement for restriction between two or more related product inventions...both two-way distinctness and reasons for insisting on restriction are necessary, i.e., separate classification, status in the art, or field of search...For other related product inventions...the inventions are distinct if (A) the inventions *as claimed* do not overlap in scope, i.e. are mutually exclusive; (B) the inventions *as claimed* are not obvious variants; and (C) the inventions *as claimed* are either not capable of use together or can have a materially different design, mode of operation, function, or effect.

With regard to the three requirements for distinctness, if the restriction fails to meet all three requirements in any aspect, then the inventions are not distinct.

According to M.P.E.P. § 806.04(f):

where two or more species are claimed a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first...

With respect to the species denoted above in the traversal, Applicant submits that, according to the standards described in the M.P.E.P., the Examiner has not described

independent or distinct species, and Applicant further submits that the purported species are not independent or distinct.

C. The Species

The Examiner has identified various elements having multiple species. There are three elements identified by the Examiner: (1) a stabilizing element; (2) a joint element; and (3) a connector element. Those species identified by the Examiner for each element are:

(1) Stabilizing element: (i) rod, (ii) plate, (iii) pivoting multi-section, and a (iv) dynamic (i.e. flexible rod);

(2) Joint element: (v) ball-and-socket; (vi) straight; (vii) tilted; (viii) offset-damped, and (ix) linearly compressible; and

(3) Connector: (x) hook and (xi) pedicle screw.

II. The Species Are Not Independent

“Two or more inventions are related (i.e., not independent) if they are disclosed as connected in at least one of design..., operation..., or effect” (M.P.E.P. § 802.01(II)).

Applicant respectfully submits that purported species (i), (ii), and (iii) are connected in not just one, but all of design, operation, and effect, and that at least purported species (i), (ii), and (iii) are not independent. All of species (i), (ii), and (iii) are stabilizing elements that share design in that a rod may be a multi-sectional rod, a plate may be a multi-sectional plate (paragraph 44), and a plate as exemplified in FIG. 11 is essentially a flattened rod. For example, paragraph 45 describes that the “stabilizing elements are typically rods *or* plates ... These rods and plates may be adapted for use ... by inserting one or more connecting joints along their lengths.” Species (i), (ii), and (iii) all operate in the same manner by supporting the stabilization system and attaching to the system via connectors. *Id.* Species (i), (ii), and (iii) all have the same effect of stabilizing the claimed stabilization systems and the spine to which they are attached. *Id.* Applicant submits that species (i), (ii), and (iii) are not independent.

Applicant submits that for the joint element, the purported species (v), (vi), (vii), and (viii) are connected in not just one of, but all of design, operation, and effect, and that at least purported species (v), (vi), (vii), and (viii) are not independent. Because, species (v), (vi), (vii), and (viii) are all described in the specification, and claimed, as pivoting joints and all share the feature of ball-and-socket, or ball-and-socket type mechanisms, they are connected in design (paragraph 48). Because, species (v), (vi), (vii), and (viii) operate by having an insert pivot within a socket, they are connected in operation (paragraph 48). Because, species (v), (vi), (vii), and (viii) provide for at least one degree of motion between segments of the spinal stabilization system, and accommodate spinal flexion and/or extension or lateral bending motion, all are connected in effect (paragraph 49). Applicant submits that species (v), (vi), (vii), and (viii) are not independent.

Applicant respectfully submits that purported species (x) and (xi) are connected in not just one of, but all of design, operation, and effect, and that at least purported species (x) and (xi) are not independent. Because, species (x) and (xi) are all described in the specification, and claimed, as connectors and all share the common features of a shaft that is adapted to penetrate or anchor to a bone and a securing portion, they are connected in design (paragraph 50). Because, species (x) and (xi) operate by connecting various elements of a spinal stabilization system to a bone, they are connected in operation. *Id.* Because, species (x) and (xi) have the effect of accommodating different orientations for the stabilizing elements to which they are attached, all are connected in effect (paragraph 51). Applicant submits that species (v), (vi), (vii), and (viii) are not independent.

Because each of the species for any recited element shares at least one of design, operation, or effect, the species are not independent.

III. The Species Are Not Distinct

As described above, distinctness is set forth in M.P.E.P. § 806.05(j). That section sets forth that inventions are distinct if (A) the inventions *as claimed* do not overlap in scope, i.e. are mutually exclusive; (B) the inventions *as claimed* are not obvious variants; and (C) the

inventions *as claimed* are either not capable of use together or can have a materially different design, mode of operation, function, or effect. Applicant submits that at least some of the present species restrictions fail to meet at least one of these requirements, when all are necessary for a showing of distinctness.

A. Species Are Not Mutually Exclusive

The species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. M.P.E.P. § 806.04(f). Stated another way, species are mutually exclusive if a first invention would not infringe a second invention and the second invention would not infringe the first invention. Applicant submits that at least some of the species within the elements identified by the Examiner are not mutually exclusive.

1. Species (i) and (iii)

The Examiner states that species (i) is a rod, exemplified in FIG. 2 (Office Action, page 2), while the specification describes the subject of FIG. 2 as “a stabilizing rod” (paragraph 21).

The Examiner states that species (iii) is a pivoting multi-section, exemplified in FIG. 13 (Office Action, page 2), while the specification describes the subject of FIG. 13 as a stabilizing element having two segments that connect (paragraph 32).

The specification, paragraph 45, describes a stabilizing element as a rod and states that the rod may have one or more connecting joints. Thus, it is clear that the two species are not mutually exclusive.

With regard to the requirements set forth above for mutually exclusive species, for at least species (iii) (i.e. a second invention), a multi-section rod would infringe a claim for species (i), a rod. Thus, by the requirements of M.P.E.P. § 806.04(f), at least species (i) and (iii) are not mutually exclusive and, therefore, not distinct.

2. *Species (ii) and (iii)*

The Examiner states that purported species (ii) is a plate, exemplified in FIG. 11 (Office Action, page 2), while the specification describes the subject of FIG. 11 as “a stabilizing plate” (paragraph 30).

The Examiner states that purported species (iii) is a pivoting multi-section, exemplified in FIG. 13 (Office Action, page 2), while the specification describes the subject of FIG. 13 as a stabilizing element having two segments that connect (paragraph 32).

The specification, paragraph 45, describes a stabilizing element as a plate and states that the plate may have one or more connecting joints. Thus, it is clear that these two species are not mutually exclusive.

With regard to the requirements set forth above for mutually exclusive species, for at least species (iii) (i.e. a second invention), a multi-section plate would infringe a claim for species (ii), a plate. Thus, by the requirements of M.P.E.P. § 806.04(f), at least species (ii) and (iii) are not mutually exclusive and, therefore, not distinct.

3. *Species (vi) and (viii)*

The Examiner states that purported species (vi) is a straight joint, exemplified in FIG. 3 (Office Action, page 2), while the specification describes the subject of FIG. 3 as “a pivoting joint” having a socket and an insert (paragraphs 22 and 62).

The Examiner states that purported species (viii) is an offset damped joint, exemplified in FIG. 9 (Office Action, page 2), while the specification describes the subject of FIG. 9 as a “stabilizing element having a damped flexion”(paragraph 28). This element is further described in paragraph 68 as “although not explicitly shown in the figures [i.e. figures 9 and 10], the first segment also includes a socket of the type shown in FIG. 2 extending into its proximal end.” Thus, it is clear from FIG. 9 that a straight joint and an offset damped joint are not mutually exclusive.

As described in paragraphs 21 and 22, FIGS. 2 and 3 are related as a posterior view and a cross-sectional view. Hence, if species (viii) *includes* species (vi), then at least a claim comprising species (vi) must be infringed by a claim comprising species (viii). At least species (vi) and (viii) are not mutually exclusive and, therefore, not distinct.

B. The Species May Be Used Together and are Connected in Design, Operation, and Effect.

“Related inventions are distinct if the inventions *as claimed* are not connected in at least one of design, operation, or effect...and wherein at least one invention is patentable...over the other” (M.P.E.P. § 802.01(II)). Under M.P.E.P. § 806.05(j), to be distinct, species must not be mutually exclusive, obvious variants, and if neither of these they may either not be capable of use together or have a materially different design, mode of operation, function, or effect. Applicant respectfully submits that a number of the purported species are connected in design and operation, and therefore are not distinct with respect to each other.

Applicant respectfully submits that purported species (i), (ii), and (iii) are connected in design, operation, and effect. As a preliminary matter, Applicant submits that the requirement that the species be *connected* in design, operation, and effect does not mean that they have to be *identical* in design, operation, and effect. As described above in section II, species (i), (ii), and (iii) are all stabilizing elements that share design as described above in that a rod may be a multi-sectional rod, a plate may be a multi-sectional plate (paragraph 44), and a plate as exemplified in FIG. 11 is essentially a flattened rod. Species (i), (ii), and (iii) all operate in the same manner as by supporting the stabilization system by attaching to the system via connectors. *Id.* Species (i), (ii), and (iii) all have the same effect of stabilizing the claimed stabilization systems and the spine to which they are attached. *Id.* For these reasons, Applicant submits that species (i), (ii), and (iii) are not distinct.

Furthermore, with regard to the stabilizing element, FIG. 8 shows more than one stabilizing element being used in a stabilization device. There is no statement prohibiting the use of purported species (i), (ii), or (iii) in the same stabilization device; thus, there can be no

assumption by the Examiner that these species could not be used together. Without a statement specifically rejecting use of the various stabilization species in the same spinal stabilization system, and in giving the claims their broadest possible interpretation, it must be assumed that the stabilization species elements could be used together. For this additional reason, Applicant submits that species (i), (ii), and (iii) are not distinct.

Applicant respectfully submits that purported species (v), (vi), (vii), and (viii) are connected in design, operation, and effect. Because species (v), (vi), (vii), and (viii) are all described in the specification, and claimed, as pivoting joints, and all share the feature of ball-and-socket, or ball-and-socket type mechanisms, they are connected in design (paragraph 48). Because species (v), (vi), (vii), and (viii) operate by having an insert pivot within a socket, they are connected in operation (paragraph 48). Because species (v), (vi), (vii), and (viii) provide for at least one degree of motion between segments of the spinal stabilization system, accommodate spinal flexion, and/or extension or lateral bending motion, all are connected in effect (paragraph 49). For these reasons, Applicant submits that species (v), (vi), (vii), and (viii) are not distinct.

Furthermore, with regard to the joint element, FIG. 8 shows more than one joint element being used in a stabilization device. There is no statement prohibiting the use of purported species (v), (vi), (vii), and (viii) in the same stabilization device; thus, there can be no assumption by the Examiner that these species could not be used together. Without a statement specifically rejecting use of the various joint species in the same spinal stabilization system, and in giving the claims their broadest possible interpretation, it must be assumed that the joint species elements could be used together. For this additional reason, Applicant submits that species (v), (vi), (vii), and (viii) are not distinct.

Applicant respectfully submits that purported species (x) and (xi) are connected in design, operation, and effect, and that at least purported species (x) and (xi) are not distinct. Because, species (x) and (xi) are all described in the specification, and claimed, as connectors and all share the common features of a shaft that is adapted to penetrate or anchor to a bone and a securing

portion, they are connected in design (paragraph 50). Because, species (x) and (xi) operate by connecting various elements of a spinal stabilization system to a bone, they are connected in operation. *Id.* Because, species (x) and (xi) have the effect of accommodating different orientations for the stabilizing elements to which they are attached, all are connected in effect (paragraph 51). For these reasons, Applicant submits that species (v), (vi), (vii), and (viii) are not distinct.

Furthermore, with regard to the connector element, paragraphs 50 and 51 describe multiple types of connectors, including those identified as species of a pedicle screw and a hook. These purported species and the others disclosed in the specification are all capable of performing the same function in the spinal stabilization system and, in fact, the systems shown in FIGS. 7 and 8 show multiple connectors. These connectors could be viewed as either of the species, and thus they can be used together. For this additional reason, Applicant submit that species (x) and (xi) are not distinct.

IV. No Serious Burden on the Examiner

The Examiner states that additional search, consideration, application of art, and time required for examination of the purported species would be a serious burden on the Examiner (Office Action, page 3). However, according to M.P.E.P. § 808.02:

[w]here the inventions as claimed are shown to be independent or distinct under the criteria of M.P.E.P. § 806.05(c) - § 806.06, the examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required. Thus the examiner must show by appropriate explanation one of the following:

- (A) Separate classification thereof...
- (B) A separate status in the art when they are classifiable together...
- (C) A different field of search...

The Examiner has not provided any of the above for any of the purported species.

As one of skill in the art will recognize from FIGS. 2 and 11, a plate is essentially a flattened rod. With regard to the multi-sectional stabilizing element of FIG. 13, it is readily seen that instead of a single piece, the multi-sectional element may be comprised of sections. The sections make up the rod or the plate; therefore, any search for the rod will include the plate and a multi-sectional stabilizing element. Any search conducted by the Examiner that is broad enough to cover the recited claim language will undoubtedly cover multi-sectional rods and plates.

Applicant submits that the ball-and-socket, straight, and tilted joints are all pivoting joints that operate using a ball-and-socket type mechanism. The purported straight and tilted species are closely related. One difference between them is in the angular disposition of the socket to its corresponding stabilization element and of the insert to its corresponding stabilization element. Paragraph 48 describes, and the independent claims recite, the joint as a “pivoting joint,” thus encompassing any of the purported ball-and-socket, straight, and tilted species. Any search conducted by the Examiner that is broad enough to cover the recited claim language would undoubtedly cover any of these purported species.

Applicant submits and has already described, in part, that a search of a species (i) should be coextensive with a search for at least species (iii) and (iv). Likewise, a search of species (v) should be coextensive with a search for at least species (vi), (vii) and (viii). Finally, given the similarity of use in the art, a search of a pedicle screw should be coextensive with that of the hook.

V. Summary

M.P.E.P. § 806 states that “the general principles relating to distinctness or independence may be summarized as follows: (A) Where inventions are independent...restriction to one thereof is ordinarily proper...(B) Where inventions are related as disclosed but are distinct as claimed, restriction may be proper...(C) where inventions are related as disclosed but are not distinct as claimed, restriction is never proper...(D) A reasonable number of species may be claimed when there is an allowable claim generic thereto.” (Emphasis added.)

Applicant submits that in view of the above remarks and the overwhelming evidence of overlap in the purported species, a number of the purported species are not independent, and a number of the purported species are not distinct. Therefore, the species election/restriction requirement is not proper, at least with respect to species (i), (ii), and (iii); species (v), (vi), (vii), and (viii); and species (x) and (xi).

If the Examiner is still of the opinion that a search for species (i), (ii), and (iii); species (v), (vi), (vii), and (viii); and species (x) and (xi) will present a serious burden upon the Examiner's time, Applicant respectfully requests the Examiner to substantiate that opinion in greater detail. In such case, Applicant requests that the Examiner specifically describe the independent and/or distinct species and why they are independent and distinct, and point out why a search of the purported species would present a burden on the Examiner. Otherwise, it is respectfully requested that the species election requirement to which the traversal applies be withdrawn, and that claims 1-25 and 43, and all of the species that were traversed by the Applicant, be examined together.

Respectfully submitted,

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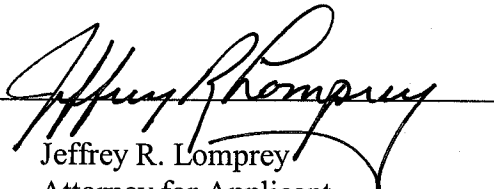
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